

REMARKS

The pending Office Action addresses claims 1, 3-13, 15-26, 28, 29, 31-44, 46-54, and 86-93. Claims 25, 29, 32, 39-44, 47, and 49-54 are withdrawn. Claims 1, 3-8, 11, 12, 15-24, 26, 28, 31, 33, 34, 36, 37, 45, 46, 48, and 86-93 stand rejected. Applicants appreciate the Examiner's indication that claims 9, 10, 13, 35, and 38 represent allowable subject matter.

Claim Amendments

Claim 86 is amended to recite that each guide member includes first and second pathways extending therethrough in substantial alignment with a distal portion of each guide member. Support for this amendment can be found throughout the specification, for example, in FIG. 5A. No new matter is added.

Rejections Pursuant to 35 U.S.C. §102

(1) U.S. Patent No. 5,067,477 of Santangelo.

Claims 86-90 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,067,477 of Santangelo.

Independent claim 86 requires that the first and second pathways extend through each guide member in substantial alignment with a distal portion of each guide member. Santangelo fails to teach first and second pathways as claimed. The arms (14, 16) in Santangelo include retractor blades (24) attached thereto that are inserted into a wound to spread tissue. As shown in FIG. 1 of Santangelo, the blades (24) are similar in shape to hooks to allow the blades to hook to the tissue around a wound to be separated. The blades do not form a guide member with first and second pathways that are in substantial alignment with a distal portion of the guide members. To the contrary, the pathways, which the Examiner argues are formed by the spacing between the blades, extend perpendicular to the axis of the arms (14, 16) of the device of Santangelo, as admitted by the Examiner on page 2 of the current Office Action.

Accordingly, claim 86, as well as claims 87-90, which depend therefrom, distinguish over Santangelo.

(2) German Patent No. 4201043 of Ulrich.

Claims 91 and 93 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by German Patent No. 4201043 of Ulrich.

In the present Office Action, the Examiner interprets “‘opposed cut-out portions’ to be with respect to one another, that is the guide members, not that there are multiple cut-outs on a single guide since that is not clear from the language of the claim.” Applicants disagree. Independent claim 91 clearly recites that *each* guide member has opposed cut-out portions formed therein. Since *each* guide member has to have opposed cut-out portions, then there must be two or more cut-outs on the *same* guide member. As explained in the previous response, Ulrich teaches a device having two arms (22’, 22”), each with a guide tube (21) attached thereto. While each of the guide tubes (21) appears to include a single cut-out portion, neither of the guide tubes (21) include *opposed* cut-out portions. Claim 91 requires both guide members to include opposed (i.e., two) cut-out portions.

Accordingly, independent claim 91, as well as claim 93 which depends therefrom, therefore distinguishes over Ulrich.

Rejections Pursuant to 35 U.S.C. §103

(1) U.S. Patent No. 7,147,599 of Phillips et al.

Claim 24 is rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 7,147,599 of Phillips et al. Claim 24 depends from claim 1 and thus includes all the features of claim 1. Phillips fails to teach or suggest a guide member having first and second pathways formed therein, as required by claim 1. Phillips is directed to a retractor device that includes first and second arms. As shown in FIG. 1, each arm includes a hook portion formed on an end thereof. While the concave space formed by the hook portion can form a single pathway, there is certainly no second pathway formed in

either of the arms of the retractor device. Thus, Phillips does not include a guide member that has first and second pathways formed therein and therefore Phillips cannot anticipate claim 24.

Claim 24 therefore represents allowable subject matter at least because it depends from claim 1.

(2) U.S. Patent No. 5,423,826 of Coates in view of U.S. Patent No. 7,147,599 of Phillips et al.

Claims 1, 3-8, 11, 12, 15-23, 26, 28, 31, 33, 34, 36, 37, 46, and 48 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,423,826 of Coates et al. in view of U.S. Patent No. 7,147,599 of Phillips et al. ("Phillips"). The Examiner relies on Coates to teach the claimed invention, but admits that Coates fails to teach that the elongate member is curved. The Examiner thus relies on Phillips to remedy this deficiency because "[i]t would have been obvious to one of ordinary skill in the art to substitute the curved support member and its attachment mechanisms for securing to arms as taught by Phillips et al. with the arms and guide members of Coates et al. such that it provides the surgeon with better or deeper access into the surgical site to implant the plate and could have the arcs of the plate match the elongate support."

There Is No Advantage To The Proposed Modification

There is no motivation to combine the teachings of Coates and Phillips as there is no advantage to adding the curved support of Phillips to the device of Coates. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP 2144). The addition of the curved support to Coates would serve absolutely no purpose. Coates discloses a drill guide including two arms (151, 152) that are pivotally coupled to one another, and a locking mechanism (153) having a threaded locking rod (155) that extends through and threadably mates to the arms (151, 152) such that rotation of the locking rod (155) pivots the arms. Each arm (151, 152) includes a foot (157) with a thru-hole(158) extending therethrough that is used to engage with a bone plate (20). The feet (157) are pivotally coupled to the arms (151, 152) to accommodate various sized plates (20). The pivotal motion of the feet relative to the arms allows the feet to engage a bone plate having any contour. Accordingly, since Coates already provides for the

ability to match the contour of the geometry of the plates using the design and pivotal attachment of the feet to the arms, there is simply no advantage to adding a curved support as taught by Phillips.

The Proposed Modification Renders The Prior Art Unsatisfactory For Its Intended Purpose

In addition, it would not have been obvious to modify Coates to include a curved support because such a modification would render Coates' device inoperable. In the present Office Action, the Examiner argues:

since the use of the curved elongated support having an arc can match the arm of the spinal plate and thus the adjustment of the arms along the elongate support can match up with that of the plate with accuracy. Additionally, the Examiner's modification was to substitute the mechanism of using the arcuate support of Phillips with the system of Coates. A substitution of adjustment of locking mechanisms is well within ordinary skill in the art and would only involve routine expertise.

Applicants disagree. M.P.E.P. 2143.01(v) expressly states that a proposed modification of a prior art invention cannot render that invention "unsatisfactory for its intended purpose." If it does, "there is no suggestion or motivation to make the proposed modification." *Id.* Substituting the threaded locking rod (155) of Coates with the arcuate support of Phillips would render the device of Coates inoperable as it would be impossible to thread a curved rod through arms that are pivotally coupled to one another. Since Coates's device could not work properly if modified to include a curved support, the combination cannot be obvious.

Accordingly, claims 1 and 26, and claims 3-8, 11, 12, 15-23, 28, 31, 33, 34, 36, 37, 46, and 48 which depend therefrom, distinguish over the combined references.

(3) *U.S. Patent No. 7,147,599 of Phillips et al. in view of U.S. Patent No. 4,887,596 of Sherman*

Claims 1, 3, and 15-19 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over Phillips in view of U.S. Patent No. 4,887,596 of Sherman. The Examiner admits that Phillips fails to disclose a

second pathway at a distal end of the guide member, but argues that it would have been obvious to add this feature as taught in Sherman.

Sherman Does Not Remedy The Deficiencies Of Phillips

At the outset, Sherman does not remedy the deficiencies of Phillips. Sherman is directed to a pedicle screw design that includes a block (21) with two set screws (22, 23) that move through the block to apply a force against a spinal rod (15) inserted through the head of the pedicle screw to hold the rod in place. The two pathways in the device of Sherman are merely the passages in the block through which the set screws advance. Sherman does not teach a guide member having first and second pathways, as required by independent claim 1. In fact, Sherman does not teach a guide member at all, but rather merely teaches the block that is inserted into the pedicle screw and having the two holes therethrough. Thus, Sherman does not teach any pathway in a guide member, and does not remedy the deficiencies of Phillips.

There Is No Advantage To The Proposed Modification

In addition, even if a second pathway was added to the arms of the Phillips' device, it would not provide any advantages to the Phillips' device. The strongest rationale for combining references is a recognition that some advantage of expected beneficial result would be produced by the combination. (See MPEP 2144). The pathway of the Phillips device is in the form of a hooked portion formed at the distal ends of the arms. Adding a pathway would involve forming a hole through the arms of the Phillips device, not the addition of another hook. Thus, this additional hole would serve absolutely no purpose. The suggested modification is therefore not obvious.

Not only would the addition of a second pathway to Phillips fail to provide stronger fastening, as suggested by the Examiner, because it would merely be a thru-hole in the arms of the Phillips device, but the modification could potentially weaken the distal ends of the arms of Phillips and ultimately decrease the effectiveness of the retraction. It is therefore not obvious to combine Phillips and Sherman

as the addition of the features taught in Sherman would only serve to make the device of Phillips worse in operation than without the modification.

The Examiner Has Failed To Establish A Prima Facie Case Of Obviousness

Additionally, in *KSR*, the operative question when considering obviousness of a combination of known elements is “whether the improvement is more than the predictable use of prior art elements according to their established function.” The claimed invention is not a predictable use of Phillips and Sherman according to their established function. Phillips discloses a tissue retractor. The established function of the device of Phillips is to separate tissue at the site of a wound to allow access for surgical procedures. Sherman, on the other hand, provides a pedicle screw. The established function of the Sherman device is to provide a mechanism to clamp a spinal rod within the head of a pedicle screw. Since the established function of each reference is entirely distinct, it would not even be predictable to combine these two references.

Phillips And Sherman Are Non-Analogous Art

Both Phillips and Sherman cannot be relied on to formulate an obviousness rejection over the pending claims because both references are non-analogous art. In order to rely on a reference in analyzing the obviousness of the subject matter at issue, the reference must be analogous prior art. A reference is “analogous” if (1) the reference is within the field of the inventor's endeavor, and if it is not then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved.

Phillips and Sherman are not within the field of the inventor's endeavor. Phillips is directed to a tissue retractor, and Sherman is directed to a pedicle screw. The present invention, on the other hand, is directed toward guide devices for implanting spinal implants. No person having ordinary skill in the art would rely on a reference directed toward tissue retractors and pedicle screws to modify a guide device for spinal implantation. These are distinct devices that are used for very different purposes.

Phillips and Sherman are also not reasonably pertinent to the problem to be solved, namely spinal fixation. Applicants refer the Examiner to MPEP 2141.01(a) and *In re Clay*, 966 F.2d 656, 659 (“A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.”) The subject matter of Phillips and Sherman would not have logically been brought to the attention of the inventor of the claimed subject matter. The present invention is directed toward a guide device for use with spinal implants. No person having ordinary skill in the art would look to a reference directed to a tissue retractor or a pedicle screw to modify a guide device as neither reference addresses the problem of guiding spinal fixation components during spinal surgery. Phillips and Sherman are therefore non-analogous art that cannot be relied on to formulate an obviousness rejection.

Accordingly, claim 1, and claims 3 and 15-19 which depend therefrom, distinguish over the combined references.

(4) German Patent No. 4201043 of Ulrich.

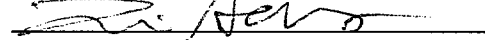
Claim 92 is rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over German Patent No. 4201043 of Ulrich. Claim 92 depends from claim 91, and thus distinguishes over Ulrich for at least the same reasons discussed above. Claim 92 therefore represents allowable subject matter at least because it depends from claim 91.

Conclusion

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

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Respectfully submitted,



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